

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 1-11 are pending in the present application. Claim 5 has been amended to address the formal matter raised in the outstanding Official Action. New claims 9-12 have been added. Support for new claims 9-10 may be found in original claim 5. Support for claim 11 may be found in original claim 1 and generally throughout the present specification.

In the outstanding Official Action, it was noted that for a patent issuing on the present application to obtain the benefit of priority based on priority papers filed in parent Application No. 10/002,417 under 35 USC §119(a)-(d) or (f), a claim for such foreign priority must be timely made in this application. Indeed, the Examiner's attention is respectfully directed to the claim to priority filed with the present application, a copy of which is provided for the Examiner's convenience. In addition, applicants note that the Application Data Sheet of the present application claims priority to U.S. Patent Application No. 10/002,417 and Swedish Application No. 0003877-8, filed on October 25, 2000. As a result, applicants believe that the present application satisfies the requirements of 37 CFR §1.55.

Claims 1-8 were rejected under the judicially created Doctrine of Obviousness-type double patenting as allegedly being unpatentable over claims 1-7 of U.S. Patent No. 6,815,436. Applicants believe that the present amendment obviates this rejection.

At this time, the Examiner's attention is respectfully directed to the Terminal Disclaimer directed to claims 1-7 of U.S. Patent No. 6,815,436. Applicants believe that the filing of the Terminal Disclaimer obviates the double patenting rejection.

In the outstanding Official Action, claim 5 was rejected for not particularly pointing out and distinctly claiming the subject matter which applicant regards as the invention. Applicants believe that the present amendment obviates this rejection.

In imposing the rejection, the Official Action stated that the term "preferably" was indefinite. However, claim 5 has been amended so that this term is no longer recited. The excised subject matter of claim 5 may now be found in claims 9 and 10.

In the outstanding Official Action, claim 1 was rejected under 35 USC §102(b) as allegedly being anticipated by IMOTO et al. Claims 2-8 were rejected under 35 USC §103(a) as allegedly being unpatentable over IMOTO et al. These rejections are respectfully traversed.

IMOTO et al. disclose a physiologically active ingredient metal salt having a bitter taste. IMOTO et al teach that the physiologically active ingredient metal salt can be mixed with aspartame in a water-soluble saccharide to reduce the bitter taste of the physiologically active ingredient metal salt. Thus, the water-soluble saccharide is added only to reduce the unpleasant taste of the aspartame.

It is believed that IMOTO et al. fail to disclose or suggest the claimed composition for delayed enzymatic degradation of starch in the gastrointestinal tract of a mammal. As noted above, IMOTO et al. is directed to an active ingredient metal salt having a bitter taste that can be mixed with aspartame in a water-soluble saccharide to reduce the bitter taste of the active ingredient. Thus, IMOTO et al. disclose that a starch may be employed as part of a chewable tablet to effectively inhibit the bitter taste of a metal salt and of a physiologically active ingredient.

While starch may be used as a filler and additive, the starch is not utilized as an active ingredient in a pharmaceutical composition. Indeed, IMOTO et al. do not teach that the starch itself can act as an active ingredient.

Applicants also note that IMOTO et al. do not teach the starch itself may be granulated. Rather, IMOTO et al teach that the composition in general may be formed into a chewable tablet or

some other form. Thus, IMOTO et al. do not teach granulating the starch per se.

As a result, there is nothing in IMOTO et al. which suggests that IMOTO et al. or any other group would regard the preparation or administration of compositions containing an effective amount of granulated starch to delay the enzymatic degradation of starch in the gastrointestinal tract of a mammal within the scope of the claims to be obvious.

In view of the above, it is believed that one of ordinary skill in the art would not consider starch as an active ingredient. One of ordinary skill in the art would consider that starch was "a pharmacologically inert" and that starch would be unsuccessful in an oral application.

The Examiner is also respectfully reminded that a pharmaceutical preparation in dosage form adapted for an administration to obtain a particular pharmacological response containing a prior art compound and a recited dosage effective to achieve that response was held unobvious in view of the prior art teaching of the compound was "pharmacologically inert and absent a teaching of the claimed amount." *In re Wiggins*, 397 F.2d 356, 158 USPQ 199 (CCPA 1968).

When considering this in combination with IMOTO et al.'s apparent failure to suggest applicants' recited amounts of granulated starch, it is believed that IMOTO et al. actually teach

away from the claimed invention and is directed to an opposite effect.

At this time, the Examiner is also respectfully reminded that a particular parameter or variable must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the parameter of variable might be characterized as routine or obvious. *In re Antonie*, 559 F.2d 618, 195 USPQ6 (CCPA 1977). See also *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Thus, while the Official Action concludes that it would be obvious to select cornstarch as opposed to native cornstarch and that the determination of the percentage weight of each individual component recited in the claimed composition would be optimized by one of ordinary skill in the art, IMOTO et al. neither disclose nor suggest that these parameters or variables would be routine or obvious to one skilled in the art. As a result, applicants believe that the Official Action fails to satisfy its burden showing that these claimed recitations would be routine or obvious to one of ordinary skill in the art.

Thus, in view of the above, it is believed that IMOTO et al fail to anticipate or render obvious the claimed invention.

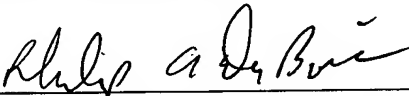
In view of the present amendment and the foregoing remarks, therefore, applicants believe that the present application has been placed in condition for allowance, with

claims 1-11, as presented. Allowance and passage to issue on that basis are respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item(s):

- a terminal disclaimer
- copy of the claim to priority made in parent application which was filed with present application, and copy of postcard receipt evidencing that it was filed with present application.